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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/639,442

08/13/2003

Benad Goldwasser

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EXAMINER

HOEKSTRA, JEFFREY GERBEN

ART UNIT

PAPER NUMBER

3736

MAIL DATE

DELIVERY MODE

08/21/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/639,442	Applicant(s) GOLDWASSER, BENAD	
	Examiner JEFFREY G. HOEKSTRA	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/29/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice of Amendment

1. In response to the amendment filed on 05/14/2008, amended claim(s) 1, and 11 is/are acknowledged. The current rejections of the claim(s) 1-15 is/are *withdrawn*. The following new and reiterated grounds of rejection are set forth:

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 07/29/2008 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statements.

3. The Examiner respectfully requests Applicant refrain from submitted identical citations multiple times in a single IDS.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1-7 and 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Choy (US 3,895,637) in view of Long et al. (US 2003/0153866 A1, hereinafter Long) in view of Ohshiro (US 4,040,414).

6. For claims 1-15, Choy discloses the claimed gastrointestinal apparatus (10) and method of use thereof, comprising:

- a guidewire (17) configured for introduction through a rectum of a subject having a distal stop (32);
- a gastrointestinal tool (18) having a chamfer and a bore (as best seen in Figures 1-4) attached to said guidewire and said gastrointestinal tool comprising a catheter (column 1 lines 5-10) having a lumen for introduction of medical instruments and fluids (column 1 lines 10-16 and 48-54) or an image viewing device (column 1 lines 10-16); and
- an inflatable device or sleeve (19) operably equipped for inflation via a channel (16) and configured to pull said guidewire away from said rectum and through a colon of a subject (column 1 lines 48-54).

7. Choy discloses the claimed gastrointestinal apparatus and methods of use thereof except for expressly disclosing (a) that after the guidewire is pulled by the inflatable device it follows that the gastrointestinal tool slides relative to said guidewire and (b) that the guidewire is slidably disposed within the bore of the gastrointestinal tool.

8. Long teaches (a) a gastrointestinal apparatus and methods of use thereof wherein after a guidewire (540) is pulled by a pulling device (500) it follows that a gastrointestinal tool (524) slides relative to said guidewire (as best seen in Figure 21) (paragraphs 46 and 47). The claimed invention would have been obvious because the substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Because both Choy and Long teach gastrointestinal apparatus and methods for traversing the gastrointestinal tract, it would have been obvious to one skilled in the art at the time of the invention to

substitute one gastrointestinal apparatus and methods for traversing the gastrointestinal tract for the other to achieve the predictable results of increasing the efficacy of a gastrointestinal traversing apparatus to navigate a tortuous gastrointestinal tract to position the apparatus for a therapeutic and/or diagnostic utility.

9. Choy in view of Long discloses the claimed invention except for expressly disclosing (b) that the guidewire is slidably disposed within the bore of the gastrointestinal tool and the gastrointestinal tool slides over the guidewire. Ohshiro teaches (b) that a guidewire is (51) slidably disposed within a bore of a gastrointestinal tool (53) and the gastrointestinal tool slides over the guidewire (as best seen in Figures 5-6). The claimed invention would have been obvious because the substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Because both Choy in view of Long and Ohshiro teach gastrointestinal apparatus and methods for traversing the gastrointestinal tract, it would have been obvious to one skilled in the art at the time of the invention to substitute one gastrointestinal apparatus and methods for traversing the gastrointestinal tract for the other to achieve the predictable results of increasing the efficacy of a gastrointestinal traversing apparatus to navigate a tortuous gastrointestinal tract to position the apparatus for a therapeutic and/or diagnostic utility.

10. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Choy in view of Long in view of Ohshiro and in further view of DeMarco (US 5,353,807).

11. Choy in view of Long in view of Ohshiro discloses the claimed gastrointestinal apparatus and methods of use thereof except for expressly disclosing the diagnostic or therapeutic tool comprising a cutting, sampling, and/or magnetic device. DeMarco teaches a gastrointestinal apparatus comprising a catheter with cutting, sampling, and magnetic devices (column 1 lines 5-53). All of the component parts are known in Choy in view of Long in view of Ohshiro and DeMarco. The only difference is the combination of the component parts into a single device. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the components as taught by Choy in view of Long in view of Ohshiro with the components as taught by DeMarco to achieve the predictable results increasing the efficacy of a gastrointestinal traversing apparatus to treat a patient by configuring it with a variety of service, therapeutic, and/or diagnostic devices.

12. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Choy (US 3,895,637) in view of Long et al. (US 2003/0153866 A1, hereinafter Long).

13. Choy discloses the claimed gastrointestinal apparatus (10) and method of use thereof, comprising:

- a guidewire (17) configured for introduction through a rectum of a subject having a distal stop (32);
- a gastrointestinal tool (18) having a chamfer and a bore (as best seen in Figures 1-4) attached to said guidewire and said gastrointestinal tool comprising a catheter (column 1 lines 5-10) having a lumen for introduction of medical instruments and

fluids (column 1 lines 10-16 and 48-54) or an image viewing device (column 1 lines 10-16); and

- an inflatable device or sleeve (19) operably equipped for inflation via a channel (16) and configured to pull said guidewire away from said rectum and through a colon of a subject (column 1 lines 48-54).

14. Choy discloses the claimed gastrointestinal apparatus and methods of use thereof except for expressly disclosing that after the guidewire is pulled by the inflatable device it follows that the gastrointestinal tool slides relative to said guidewire. Long teaches a gastrointestinal apparatus and methods of use thereof wherein after a guidewire (540) is pulled by a pulling device (500) it follows that a gastrointestinal tool (524) slides over (i.e. above) and relative to said guidewire (as best seen in Figure 21) (paragraphs 46 and 47). All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. All of the component parts are known in Choy and Long. The only difference is the combination of the component parts into a single device. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the components as taught by Choy with the components as taught by Long to achieve the predictable results increasing the efficacy of a gastrointestinal traversing apparatus to treat a patient by configuring it with a variety of service, therapeutic, and/or diagnostic devices.

Response to Arguments

15. Applicant's arguments with respect to claims 1-15 have been considered but are moot in view of the new ground(s) of rejection.

16. Applicant's arguments filed 05/14/2008 have been fully considered but they are not persuasive. Applicant argues the rejection of claim 16 under 35 U.S.C. 103(a) as being unpatentable over Choy in view of Long, specifically arguing:

- (a) "Applicant hereby confirms that the intended scope of all of the claims, including claim 16, relates to a guidewire that is within the bore of the gastrointestinal tool during use, and that the meaning of sliding the tool over the guidewire does not include within its scope a situation where the tool is simply above the guidewire (i.e., where the tool is at a higher height than the guidewire). The Applicant notes that it is the Applicant's belief that Fig. 21 of Long et al. does not show a tool passing over a guidewire, using the normal understanding of the meaning of "passing a tool over a guidewire" as used by a person of ordinary skill in the art of GI tract tools." and
- (b) neither Choy nor Long teach "wherein said guidewire is pulled by said inflatable device and following pulling of said guidewire by said inflatable device, said gastrointestinal tool slides relative to said guidewire."

17. The Examiner disagrees, maintains the rejection as broadly as claimed as reiterated above, and in response notes the following:

18. In response to Applicant's argument (a) that Long does not show a tool passing "over" a guidewire, the Examiner notes Attorney's argument is not the kind of factual

evidence that is required to rebut a prima facie case (MPEP 2145) and absent any special definition in the instant Specification and as broadly as claimed Applicant appears to heavily rely on "sliding the tool over the guidewire" for a patentability. The Examiner notes under the broadest reasonable interpretation and under the plain definition of over (i.e. where the tool is at a higher height than the guidewire) Long discloses the claimed limitations and remedies the deficiencies of Choy as set forth above. The Examiner notes for example the claim does not positively recite "sliding a gastrointestinal tool over the outer surface and relative to the guidewire" or the like.

19. In response to Applicant's argument (b) that Long does not show a tool sliding relative the guidewire after the guidewire is pulled by the inflatable device, the Examiner notes (as cited above) Long teaches a slideable gastrointestinal tool for medical intervention that is introduced and removed over and relative to the guidewire after the guidewire is pulled by the inflatable device to the desired gastrointestinal location (as best seen in Figure 21).

20. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Conclusion

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY G. HOEKSTRA whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/J.H./
Jeff Hoekstra
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736